K032444

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CardinalHealth

XIII. SUMMARY OF SAFETY AND EFFECTIVENESS

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
NITRILE POWDER-FREE EXAMINATION GLOVES WITH COATING

Applicant/Sponsor: Cardinal Health
1500 Waukegan Road
McGaw Park, IL 60085

Regulatory Affairs Contact: Erica Sethi
Cardinal Health
1500 Waukegan Road, Bldg. WM
McGaw Park, IL 60085

Telephone: (847) 785-3337

Date Summary Prepared: 7/25/03

Product Trade Name: Undetermined

Common Name: Examination Glove

Classification: Patient Examination Glove

Predicate Devices: Nitrile Powder-Free Examination Gloves, Cardinal Health.

Description: Nitrile Powder-Free Examination Gloves with coating are formulated using nitrile and offered powder-free.

Intended Use: These examination gloves are disposable devices intended for medical purposes that are worn on the examiner's hands or fingers to prevent contamination between patient and examiner. In addition, these gloves are worn to protect the wearer against exposure to chemotherapy drugs.

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Substantial Equivalence: Nitrile Powder-Free Examination Gloves with Coating are substantially equivalent to Cardinal Health's Nitrile Powder-Free Examination Gloves in that they provide the following characteristics:

- same intended use
- same sizes
- both made of nitrile
- both offered beaded and powder-free
- both worn to protect the wearer against exposure to chemotherapy drugs

Summary of Testing:

Test	Result
Primary Skin Irritation	Gloves show no irritation.
Guinea Pig Maximization	Gloves do not display any potential for irritation.
Tensile Strength	Gloves meet or exceed requirements per ASTM D6319-00a^{e3}.
Barrier Defects	Gloves meet or exceed requirements per 21 CFR§800.20 and ASTM D6319-00a^{e3}.
Chemotherapy testing	Tested for chemotherapy drugs using ASTM F739-99a

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 3 2003

Cardinal Health
C/O Ms. Erica Sethi
Manager, Regulatory Affairs
Medial Product and Services
1500 Waukegan Road Bldg WM
Mcgaw Park, Illinois 60085

Re: K032444
Trade/Device Name: Nitrile Powdered- Free Examination Glove with Lotion Coating And use for Chemotherapy
Regulation Number: 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZC
Dated: October 23, 2003
Received: October 30, 2003

Dear Ms. Sethi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594- 4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

CardinalHealth

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Susanna F. Barnes
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K032444

Applicant: Cardinal Health

510(k) Number: K032444

Device Name: Undetermined

Indications For Use: A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. In addition, these gloves are worn to protect the wearer against exposure to chemotherapy drugs.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ or Over-The Counter Use X
(Per 21 CFR 801.109)